

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : Franks et al.
SERIAL NO. : 10/524,316
FILED : February 9, 2005
FOR : ANALGESIC AGENT FOR NEWBORN OR FETAL
SUBJECTS
EXAMINER: E. Arnold
GROUP ART UNIT : 1616

COMMISSIONER FOR PATENTS
P.O. BOX 1450
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DECLARATION UNDER 37 C.F.R. 1.132

SIR:

I, Dr. Mervyn Maze, declare as follows:

1. I am Head of the Department of Anaesthetics, Pain Medicine, and Intensive Care at Imperial College in London, England, a position I have held since July 2000. Prior to that I was Deputy Head of the Department of Anesthesiology, Stanford University, California.
2. I received a MB ChB degree (conferred with Honours) from University of Cape Town in December 1970.

3. I am familiar with medical procedures used to diagnose organ anomalies in humans as well as in rats during research studies.
4. I am the co-inventor of the above-identified application and have reviewed it as well as the Office Action of October 24, 2008. I have also reviewed the reference, Lane et al., "Anesthetics as Teratogens: Nitrous Oxide is Fetotoxic, Xenon is not," Science, Vol. 210, No. 4472 (Nov. 21, 1980) ("Lane").
5. Lane describes examining "macroscopic organ anomalies" in rats after administration of xenon and nitrous oxide. The specific anomalies that were examined in Lane were encephalocele, hydrocephalus, anophthalmia, microphthalmia, microphthalmia, cleft lip/palate, gastroschisis, gonadal agenesis, undescended testis, and shortened limbs. I am familiar with all of these conditions and can attest that these conditions can be diagnosed in rats by visual inspection. The rats do not need to undergo any painful or invasive procedures, which would necessitate administration of an analgesic, to diagnosis these conditions. Indeed, an analgesic agent would not be administered to rats prior to examining the presence or absence of these conditions.
6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the patent or any reexamination certificate issued therefor.



Dated: 27 January 2009

Mervyn Maze